

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Laura Manteuffel,

Case No. 0:10-cv-04026-JRT-LIB

Plaintiff,

v.

DePuy Orthopaedics, Inc., et al.,

Defendants.

**DEFENDANTS DEPUY ORTHOPAEDICS, INC. AND
JOHNSON & JOHNSON'S ANSWER AND DEFENSES
TO PLAINTIFF'S COMPLAINT
AND DEMAND FOR JURY TRIAL**

Defendants DePuy Orthopaedics, Inc. and Johnson & Johnson ("Defendants") respond to the allegations set forth in Plaintiff's Complaint as follows. The repetition of some of the Complaint's subheadings is done solely for organizational purposes and is not an admission as to their truth.

INTRODUCTION

1. Defendants admit that Plaintiff has brought an action for damages in connection with her alleged experience with what she terms the DePuy ASR™ XL Acetabular Hip Replacement System ("ASR™ XL System") and the ASR™ Hip Resurfacing System. Defendants deny the remaining allegations contained in Paragraph 1.

PARTIES

2. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 and therefore deny them.

3. Defendants admit that DePuy Orthopaedics, Inc. is an Indiana corporation with its principal place of business in Warsaw, Indiana and that DePuy is the responsible U.S. entity for the design, manufacture, label, distribution, and sale of the ASR[™] XL System and the ASR[™] Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 3.

4. Defendants admit that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Defendants deny the remaining allegations contained in Paragraph 4 as phrased.

5. Defendants deny the allegations contained in Paragraph 5.

6. Paragraph 6 contains no factual allegations requiring a response.

JURISDICTION AND VENUE

7. Defendants specifically deny that Plaintiff is entitled to damages but admit that this Court has jurisdiction over this matter. Defendants deny all remaining allegations contained in Paragraph 7.

8. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 and therefore deny them.

FACTUAL BACKGROUND

9. Defendants admit that the description of the hip anatomy is superficially accurate. Defendants deny the remaining allegations contained in Paragraph 9 as phrased.

10. Defendants deny the allegations contained in Paragraph 10 as phrased.

11. Defendants deny the allegations contained in Paragraph 11 as phrased.

12. Defendants admit that the ASR™ XL System and the ASR™ Surface Replacement femoral head component are Class III medical devices as defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 12.

13. The Medical Device Amendments speak for themselves. Defendants deny the remaining allegations contained in Paragraph 13 as phrased.

14. Defendants admit that the requirements of the pre-market approval process are defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 14 as phrased.

15. Defendants admit that the requirements of the pre-market approval process are defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 15 as phrased.

16. Defendants admit that the processes for FDA marketing approval, before the effective date of the Medical Device Amendments, are defined under the applicable

federal regulations. Defendants deny the remaining allegations contained in Paragraph 16 as phrased.

17. Defendants admit that the 510(k) clearance process is defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 17 as phrased.

18. Defendants admit that the 510(k) clearance process is a process through which manufacturers of medical devices can obtain FDA marketing clearance. Defendants deny the remaining allegations contained in Paragraph 18 as phrased.

19. Defendants admit that DePuy began selling the ASR™ XL System in the U.S. in 2005. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 19 and therefore deny them.

20. Defendants admit that the 510(k) clearance process is defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 20 as phrased.

21. Defendants admit that the FDA cleared the ASR™ XL System for sale in the United States pursuant to the 510(k) process, which is based in part on a finding of substantial equivalence to devices previously cleared by the FDA, and that the ASR™ XL System was not required by the FDA to undergo clinical trials as a part of this process. Defendants deny the remaining allegations contained in Paragraph 21.

22. Defendants admit that the FDA cleared the ASR™ XL System for sale in the United States pursuant to the 510(k) process, which is based in part on a finding of substantial equivalence to devices previously cleared by the FDA, and that the ASR™ XL System was not required by the FDA to undergo clinical trials as a part of this process. Defendants deny the remaining allegations contained in Paragraph 22.

23. Defendants admit that in 2005 the FDA cleared the ASR™ XL System for sale in the United States pursuant to the 510(k) process, which is based in part on a finding of substantial equivalence to devices previously cleared by the FDA, and that the ASR™ XL System was not required by the FDA to undergo clinical trials as a part of this process. Defendants deny the remaining allegations contained in Paragraph 23.

24. Defendants deny the allegations contained in Paragraph 24 as interpreted, phrased, and incompletely presented.

25. Defendants admit that the 510(k) clearance process is defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 25 as phrased.

26. Defendants admit that the 510(k) clearance process is defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 26 as phrased.

27. Defendants deny the allegations contained in Paragraph 27 as interpreted, phrased, and incompletely presented.

28. Defendants deny the allegations contained in Paragraph 28 as interpreted, phrased, and incompletely presented.

29. Defendants admit that the acronym “ASR” stands for “Articular Surface Replacement.” Defendants further admit that the description of the difference between a total hip replacement procedure and a surface replacement procedure is superficially accurate. Defendants deny the remaining allegations contained in Paragraph 29 as phrased.

30. Defendants admit that the processes for FDA approval of medical devices are defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 30.

31. Defendants deny the allegations contained in Paragraph 31 as phrased and incompletely presented.

32. Defendants deny the allegations contained in Paragraph 32.

33. Defendants admit that a component of the ASR™ XL Acetabular Hip Replacement System and the ASR™ Hip Resurfacing System is a metal acetabular cup. Defendants deny the remaining allegations contained in Paragraph 33.

34. Defendants deny the allegations contained in Paragraph 34 as interpreted, phrased, and incompletely presented.

35. Defendants lack knowledge or information sufficient to form a belief as to what Dr. Graves believed at undefined points in time and therefore deny these allegations. Defendants deny the remaining allegations contained in Paragraph 35.

36. Defendants lack knowledge or information sufficient to form a belief as to what Dr. Amstutz said at an undefined point in time and therefore deny these allegations. Defendants deny the remaining allegations contained in Paragraph 36.

37. Defendants admit that the New York Times published an article on March 10, 2010 concerning the ASR™ XL System. Defendants deny the remaining allegations contained in Paragraph 37 as interpreted, phrased, and incompletely presented.

38. Defendants deny the allegations contained in Paragraph 38.

39. Defendants deny the allegations contained in Paragraph 39 as phrased.

40. Defendants admit that DePuy issued a Field Notification Letter dated March 6, 2010 concerning data from the Australian National Joint Replacement Registry. Defendants further admit that they were discontinuing sale of the ASR™ XL System worldwide on a market-by-market basis. Defendants deny the remaining allegations contained in Paragraph 40 as phrased.

41. Defendants admit that a Class 2 Recall is defined under the applicable federal regulations. Defendants deny the remaining allegations contained in Paragraph 41 as phrased.

42. Defendants admit that DePuy's August 2010 recall communications reference unpublished data from the National Joint Registry of England and Wales. Defendants deny the remaining allegations contained in Paragraph 42 as interpreted and phrased.

43. Defendants admit that DePuy's August 2010 recall communications reference unpublished data from the National Joint Registry of England and Wales. Defendants deny the remaining allegations contained in Paragraph 43 as interpreted and phrased.

44. Defendants admit that DePuy issued a voluntary, global recall of the ASR™ XL System and the ASR™ Hip Resurfacing System. Defendants deny the remaining allegations contained in Paragraph 44 as phrased.

45. Defendants deny the allegations contained in Paragraph 45.

46. Defendants lack knowledge sufficient to form a belief as to the truth of the allegations concerning Plaintiff's alleged surgical procedure "to implant an ASR™ Hip" and therefore deny them. Defendants deny the remaining allegations contained in Paragraph 46.

47. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 47 and therefore deny them.

48. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 48 and therefore deny them.

49. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 49 concerning Plaintiff's alleged revision surgery and therefore deny them. Defendants deny the remaining allegations of Paragraph 49.

50. Defendants deny the allegations contained in Paragraph 50.

51. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 and therefore deny them.

52. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52 and therefore deny them.

53. Defendants admit that the medical literature speaks for itself. Defendants deny the allegations contained in Paragraph 53 as interpreted, phrased, and incompletely presented.

54. Defendants admit that this Court has jurisdiction of this matter but deny the remaining allegations contained in Paragraph 54 of the Complaint.

COUNT I

(Strict Products Liability – Failure to Warn)

55. Defendants reallege their answers to all other paragraphs of Plaintiff's Complaint.

56. Defendants admit that DePuy is the responsible U.S. entity for the design, manufacture, labeling, distribution, and sale of the ASR™ XL System and the ASR™

Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 56.

57. Defendants deny the allegations contained in Paragraph 57.

58. Defendants deny the allegations contained in Paragraph 58.

59. Defendants deny the allegations contained in Paragraph 59.

60. Defendants deny the allegations contained in Paragraph 60.

61. Defendants deny the allegations contained in Paragraph 61.

62. Defendants deny the allegations contained in Paragraph 62.

COUNT II

(Strict Products Liability – Defective Design)

63. Defendants reallege their answers to all other paragraphs of Plaintiff's Complaint.

64. Defendants admit that DePuy is the responsible U.S. entity for the design, manufacture, labeling, distribution, and sales of the ASR™ XL System and the ASR™ Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 64.

65. Defendants deny the allegations contained in Paragraph 65.

66. Defendants deny the allegations contained in Paragraph 66.

67. Defendants lack knowledge or information sufficient to form a belief as to the condition in which the product at issue reached the Plaintiff and therefore deny those allegations. Defendants deny the remaining allegations contained in Paragraph 67.

68. Defendants lack knowledge or information sufficient to form a belief as to Plaintiff's state of knowledge at any given time, how the product was utilized, or any representations that may have been made to her, and therefore deny those allegations. Defendants deny the remaining allegations contained in Paragraph 68.

69. Defendants deny the allegations contained in Paragraph 69.

70. Defendants deny the allegations contained in Paragraph 70.

71. Defendants deny the allegations contained in Paragraph 71.

COUNT III

(Breach of Express Warranty)

72. Defendants reallege their answers to all other paragraphs of Plaintiff's Complaint.

73. Defendants admit that DePuy is the responsible U.S. entity for the design, manufacture, labeling, distribution, and sales of the ASR™ XL System and the ASR™ Surface Replacement femoral head component. Defendants deny the remaining allegations contained in Paragraph 73.

74. The allegations in Paragraph 74 of Plaintiff's Complaint constitute legal conclusions and therefore do not require a response. To the extent a response is required, Defendants deny the allegations contained in Paragraph 74.

75. Defendants deny the allegations contained in Paragraph 75.

76. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 76 and therefore deny them.

77. Defendants deny that they breached any alleged warranty to Plaintiff or her physician. Defendants deny the remaining allegations contained in Paragraph 77 as phrased.

78. Defendants deny the allegations contained in Paragraph 78.

79. Defendants deny the allegations contained in Paragraph 79.

COUNT IV

(Breach of Implied Warranty)

80. Defendants reallege their answers to all other paragraphs of Plaintiff's Complaint.

81. Defendants deny the allegations contained in Paragraph 81.

82. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 82 and therefore deny them.

83. Defendants deny that they breached any alleged warranty to Plaintiff or her physician. Defendants deny the remaining allegations contained in Paragraph 83 as phrased.

84. Defendants deny the allegations contained in Paragraph 84.

85. Defendants deny the allegations contained in Paragraph 85.

COUNT V

(Negligence)

86. Defendants reallege their answers to all other paragraphs of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 as phrased.

88. Defendants deny the allegations contained in Paragraph 88.

89. Defendants deny the allegations contained in Paragraph 89.

90. Defendants deny the allegations contained in Paragraph 90.

91. As to the unnumbered prayer for relief under Paragraph 90 of Plaintiff's Complaint, Defendants deny that Plaintiff is entitled to the requested damage and other relief awards.

FIRST AFFIRMATIVE DEFENSE

92. Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case and such assumption of the risks bars in whole or in part the damages Plaintiff seeks to recover herein.

SECOND AFFIRMATIVE DEFENSE

93. At all times mentioned herein, Plaintiff was negligent, careless and at fault, and conducted herself so as to contribute substantially to her alleged injuries and damages. Said negligence, carelessness, and fault of Plaintiff bars in whole or in part the damages which Plaintiff seeks to recover herein.

THIRD AFFIRMATIVE DEFENSE

94. Plaintiff's alleged injuries attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FOURTH AFFIRMATIVE DEFENSE

95. Plaintiff's alleged damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages.

FIFTH AFFIRMATIVE DEFENSE

96. Plaintiff's causes of action are barred by the applicable statutes of limitation.

SIXTH AFFIRMATIVE DEFENSE

97. Defendants did not make to Plaintiff nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiff relied on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendants and/or for failure of Plaintiff, or Plaintiff's representatives, to give timely notice to Defendants of any alleged breach of warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

SEVENTH AFFIRMATIVE DEFENSE

98. At the time of sale or delivery, the products conformed to state-of-the-art for such products at that time.

EIGHTH AFFIRMATIVE DEFENSE

99. Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

NINTH AFFIRMATIVE DEFENSE

100. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

TENTH AFFIRMATIVE DEFENSE

101. Plaintiff's causes of action are barred by the learned intermediary doctrine.

ELEVENTH AFFIRMATIVE DEFENSE

102. Plaintiff's claims are barred by the doctrines of informed consent, release, and waiver.

TWELFTH AFFIRMATIVE DEFENSE

103. Defendants allege that Plaintiff's claim for punitive or exemplary damages is unconstitutional in that recovery of punitive or exemplary damages in this case would violate Defendants' constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the Minnesota, Indiana, and New Jersey state constitutions, and any other state whose law is deemed to apply in this case, and that any law of the states of Minnesota, Indiana, or New Jersey whether enacted by that state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is unconstitutional under these provisions.

THIRTEENTH AFFIRMATIVE DEFENSE

104. Defendants allege that Plaintiff's claim for punitive or exemplary damages is unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against Defendants for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of Defendants' property without due process of law and will result in unjustified windfalls for Plaintiff and Plaintiff's counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the Minnesota, Indiana, and New Jersey state constitutions, and that of any other state whose law is deemed to apply in this case.

FOURTEENTH AFFIRMATIVE DEFENSE

105. Plaintiff's claim for punitive damages against Defendants cannot be maintained because an award of punitive damages under current Minnesota, Indiana, and New Jersey law, and any other state's law deemed to apply to this action, would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time

the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Eighth and Fourteenth Amendments to the United States Constitution, the due process provisions of the Minnesota, Indiana, and New Jersey state constitutions, and the common law and public policies of the states of Minnesota, Indiana, and New Jersey and similar protections afforded by any other state whose law is deemed to apply in this case.

FIFTEENTH AFFIRMATIVE DEFENSE

106. To the extent that the laws of Minnesota, Indiana, New Jersey, and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of Defendants and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of Defendants in other states, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, the state laws and constitutional provisions of Minnesota, Indiana, and New Jersey and similar protections afforded by any other state whose law is deemed to apply in this case.

SIXTEENTH AFFIRMATIVE DEFENSE

107. Under Minnesota Law, Plaintiff is prohibited from alleging punitive damages in her complaint until and unless a court determines, following a hearing on a motion to amend the pleadings, that the Plaintiff has presented prima facie evidence of entitlement to punitive damages. If the Court were to grant such a motion to amend, Defendants are entitled to the protections and limitations afforded under Minn. Stat. § 549.20.

SEVENTEENTH AFFIRMATIVE DEFENSE

108. Defendants are entitled to the protections and limitations afforded under Ind. Code Ann. §§ 34-51-3-1, *et seq.*

EIGHTEENTH AFFIRMATIVE DEFENSE

109. Defendants are entitled to the protections and limitations afforded under the New Jersey Punitive Damages Act, N.J.S.A. §§ 2A:15-5.9, *et seq.* and the New Jersey Product Liability Act, N.J.S.A. §§ 2A:58C-1, *et seq.*

NINETEENTH AFFIRMATIVE DEFENSE

110. Defendants are entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in any state whose law is deemed to apply in this case.

TWENTIETH AFFIRMATIVE DEFENSE

111. The claims of Plaintiff should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence and the Joint Tortfeasor Contribution Act.

TWENTY-FIRST AFFIRMATIVE DEFENSE

112. The injuries and damages claimed by Plaintiff, if any, were caused in whole or in part by the acts or omissions of persons over whom Defendants have no control or right of control.

TWENTY-SECOND AFFIRMATIVE DEFENSE

113. Plaintiff's claims are barred by the equitable doctrines of laches and estoppel.

TWENTY-THIRD AFFIRMATIVE DEFENSE

114. Upon information and belief, if the injuries referred to in the Complaint were caused by Defendants' products, which are denied, the injuries are the result of an idiosyncratic reaction to the products.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

115. Plaintiff's alleged injuries are a result of a pre-existing and/or unrelated medical condition for which Defendants are not responsible.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

116. To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v.*

Plaintiff's Legal Comm., 531 U.S. 341 (2001).

TWENTY-SIXTH AFFIRMATIVE DEFENSE

117. If Defendants' products are unsafe in any way, they are unavoidably unsafe. Plaintiff's purported action is, therefore, barred by cmt. k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

118. Defendants reserve their right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substance of law.

WHEREFORE, these answering Defendants pray that Plaintiff takes nothing by reason of her pretended Complaint and that Defendants have judgment for their costs and disbursements incurred herein.

TRIAL BY JURY IS HEREBY DEMANDED

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Defendants hereby request a trial by jury, composed of the maximum number of jurors allowed by law, on all issues so triable.

Dated: October 19, 2010

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